

**Food and Drug Administration
Budget Hearing
April 26, 2013
Chairman Robert Aderholt
Opening Statement**

Good morning. I would like to welcome to the subcommittee today, Dr. Margaret Hamburg, the Commissioner of the Food and Drug Administration (FDA). Joining Commissioner Hamburg is Mr. Norris Cochran, the Deputy Assistant Secretary for Budget of the U.S. Department of Health and Human Services, and Jay Tyler, FDA's Chief Financial Officer.

The work that you and your colleagues at FDA perform touches the lives of every American, and we appreciate the dedicated service of you and your colleagues. With that said, there are many challenges facing the FDA. Compounding pharmacies, drug shortages, foodborne illnesses, and dietary supplements are just some of those challenges.

From where I sit, I see another challenge, and that is the pace at which FDA moves guidance, rules, and regulations through the process. In addition to the budget request, I want to focus today on this bureaucracy that just can't seem to produce crucial guidance even though the science is evident. For example, USDA's Dietary Guidelines for Americans on seafood consumption for women who are pregnant have been in place since January 2011. However, for the past two years, this subcommittee has repeatedly asked FDA to finalize its seafood consumption guidance, with no indication of closure because this issue is tied up in bureaucratic infighting at HHS. This type of delayed response causes frustration with Congress as well as the millions of women who need answers on this and other important matters.

Turning to the budget, I don't quite understand why the budget was submitted so late given the fact that the basis for the request was the FY 2013 Continuing Resolution that was signed into law on September 28, 2012. The result is a simple repeat of last year's budget. This budget could have been submitted much earlier, and there would be more clarity regarding the President's request than there is right now. On Monday of this week, we asked FDA to provide something as simple as a table that shows the proposed changes between the final FY 2013 enacted level and the FY 2014 budget request level. The other agencies within the subcommittee's jurisdiction provided the Committee with this information more than two weeks ago. On the other hand, FDA only provided this information long after the sun went down last night. This is basic budgetary information that FDA should have either provided to the subcommittee without asking, or FDA should have provided it upon request and without delay.

Overall, FDA is requesting \$4.7 billion for FY 2014 of which \$2.6 billion is in discretionary budget authority, and \$2.1 billion is in user fees. Once again, FDA is requesting new user fee authority for food imports and food facility registration and inspection. These particular fees total \$226 million. These fees do not appear to enjoy the same level of industry support that the prescription drug or medical device industries give to their programs because the food industry believes this to be a "food safety tax". The FDA has failed to communicate to industry what, if any, performance measurements FDA would use in managing this program. These fees are not authorized, and the chance of Congress authorizing them seems slim.

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